U.S. Department of Justice
Civil Division, Federal Programs Branch

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Via ECF

Hon. Paul W. Grimm
U.S. District Court for the District of Maryland

Re: *American Academy of Pediatrics v. FDA*, No. 8:18-cv-883-PWG

Dear Judge Grimm:

In accordance with the Court's letter order regarding the filing of motions, ECF No. 15, Defendants respectfully request permission to file a motion: (a) for clarification that the Court's remedy order, ECF No. 127, does not prohibit the FDA from deferring enforcement of the Tobacco Control Act's premarket authorization requirement, 21 U.S.C. § 387j, against premium cigars on a case-by-case basis as described below; or (b) in the alternative, for relief from the remedy order under Federal Rule of Civil Procedure 60(b).

Under the remedy order as amended, the FDA must require that all premarket applications for deemed new tobacco products on the market as of the deeming rule's effective date be filed by September 9, 2020. ECF No. 127 at 12, *as amended*, ECF No. 182. The remedy order provides, however, that the FDA can "exempt [n]ew [tobacco] [p]roducts from [this] filing requirement[] for good cause on a case-by-case basis." ECF No. 127 at 12. The Court's summary judgment opinion likewise recognizes that "as a matter of its 'enforcement discretion,' the FDA may decide not to enforce the provisions of the Tobacco Control Act with regard to specific products." ECF No. 73 at 45 (citation omitted). The FDA's retained discretion in this respect is at its greatest, the Court stated, when the agency makes enforcement decisions to "fulfill the purpose for which an agency is granted enforcement discretion" — namely, to "balanc[e]" factors like "whether agency resources are best spent on this violation or another," "whether the particular enforcement action requested best fits the agency's overall policies," and "whether the agency has enough resources to undertake the action at all." *Id.* at 45–46 (quoting *Heckler v. Chaney*, 470 U.S. 821, 831–32 (1985)). Consistent with that discretion, the FDA previously issued guidance in January 2020 explaining its current enforcement priorities and identifying types of products that would likely represent the highest and lowest priorities for enforcement. *See* ECF No. 174-1.

The FDA intends to exercise its retained discretion by deferring enforcement of the premarket authorization requirement for premium cigar manufacturers and importers on a case-by-case basis. The deferrals are intended to help prioritize the use of the FDA's limited enforcement resources while the agency undertakes a new research effort to evaluate the public health impact of premium cigars. The FDA intends to describe how manufacturers and importers can submit deferral requests in a guidance document that would take effect immediately upon issuance.

The FDA's top priority for premarket review of deemed products remains products that pose the greatest risk for initiation or use by underage persons, such as flavored, cartridge-based e-cigarette products targeted to or easily accessible to youth. Because the FDA's current information indicates that youth smoke premium cigars comparatively less than most other deemed tobacco

products, like e-cigarettes, premium cigars remain the FDA's lowest priority for premarket review. At the same time, premium cigars are made in many varieties with thousands of stock units, which could entail a large influx of premarket applications for premium cigars on the market as of the deeming rule's effective date. The forthcoming guidance will allow the FDA to focus its limited enforcement resources on premarket applications for other types of deemed products posing greater risk for youth initiation or use (of which the FDA anticipates receiving a significant volume by the September 9, 2020 deadline).[1]

In addition, the FDA has received numerous comments that, given their use patterns, premium cigars pose lower risks to individual and public health than other tobacco products. Perhaps because of the relatively small market for premium cigars, however, the comments received by the FDA to date — both in favor of and against regulation of premium cigars — have not provided new data sufficient to address questions of whether the characteristics of premium cigars or their patterns of use may result in different health effects than other tobacco products. The FDA thus intends to undertake a research effort specific to premium cigars and their health effects, patterns of use (such as frequency of use and usage patterns among underage persons), and other factors. The FDA plans to seek broad public comment on the research plan and anticipates that the research will not only comprehensively assess the existing scientific evidence on these topics, but also generate new, high-quality scientific evidence. The results of this research will inform the FDA's regulatory policy with respect to premium cigars, including the public health impact and regulatory impact associated with premarket review of premium cigars. The FDA intends to regularly update the public about the status of the research project.

To help the FDA appropriately focus its enforcement efforts, the agency intends to describe in a guidance how manufacturers and importers of premium cigars may, on a case-by-case basis, request deferral of enforcement of the premarket authorization requirement for products meeting the definition of premium cigars set forth in the guidance[2] and for which the manufacturer's marketing does not and will not target underage persons or involve practices likely to promote use of the products by underage persons. Manufacturers may request deferral irrespective of whether a

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[1] E-cigarette products targeted to or easily accessible to youth continue to require substantial FDA efforts, as the FDA anticipated in its January 2020 enforcement guidance. ECF No. 174-1 at 30–31. The FDA has issued numerous warning letters to flavored and cartridge-based e-cigarette manufacturers, including 10 such letters on July 20, 2020, as well as several since. *See* Warning Letters, U.S. Food & Drug Administration, *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters (issuing office: Center for Tobacco Products) (last visited July 28, 2020).

[2] The guidance will define a "premium cigar" as a cigar that: (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7) contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units. This definition is consistent with the description in the January 2020 guidance, ECF No. 174-1, and similar to the definition in the proposed deeming rule, 79 Fed. Reg. 23,142, 23,150 (2014).

product was on the market as of the deeming rule's effective date. The guidance will advise that each deferral request should include: (1) the name and address of the tobacco product manufacturer or importer submitting the request; (2) the name, telephone number, and email address for a point of contact for that manufacturer or importer; (3) for foreign-manufactured products, the name, telephone number, and email address for a point of contact at the foreign manufacturer; (4) information that identifies the product(s) for which deferral is requested, including the brand name, sub-brand, and unique identifiers (e.g., TP Number, SKU, catalogue number, UPC, package type, cigar length, cigar diameter) of each premium cigar product for which the deferral is requested; (5) a certification, signed and dated by an authorized official of the manufacturer or importer, that the listed product(s) meet the definition of "premium cigar" set forth in the guidance; (6) a certification that the manufacturer or importer does not and will not target underage persons or use marketing practices likely to promote use of the product(s) by underage persons; and (7) additional information, if any, that the manufacturer or importer believes may further enable the FDA to determine whether the deferral request is consistent with the goals of the guidance, such as information describing how the product(s) is within the scope of the definition of premium cigar or a description of the manufacturer's or importer's actions to prevent youth access to, and use of, the product(s). The FDA will review each request and decide on a case-by-case basis whether good cause supports the request. Because the FDA intends in the guidance to clarify that the subclass of products for which deferral will be considered is narrowly tailored to those expected to be the subject of the research effort and for which the manufacturer's marketing does not and will not target underage persons or involve practices likely to promote the use of the products by underage persons, the agency anticipates that many, if not all, manufacturers of premium cigars who submit the requested information will be able to show that deferral is appropriate. When the FDA determines that deferral for a particular premium cigar product is appropriate, the agency intends to send an acknowledgement letter and then defer enforcement until it has completed the premium cigar research effort and assessed the results. However, the FDA retains discretion to pursue enforcement action at any time against any deemed new tobacco products marketed without premarket authorization, including products that do not meet the definition of premium cigar or whose manufacturers target underage persons.

Because the policy announced in the forthcoming guidance will entail individualized determinations about specific products to best prioritize the FDA's limited enforcement resources in light of the agency's broader tobacco policies, the guidance constitutes the kind of "case-by-case" enforcement discretion retained by the FDA under the Court's remedy order. ECF No. 127 at 12. However, out of an abundance of caution and because Plaintiffs have indicated their contrary view, Defendants seek clarification from the Court that the FDA may, consistent with the remedy order, defer enforcement under the circumstances described in this letter. In the alternative, if the Court determines that such deferred enforcement is inconsistent with the remedy order, Defendants respectfully request modification of the remedy order under Rule 60(b).

Defendants conferred about the relief requested in this letter with Plaintiffs, who indicated that they oppose the relief and request an opportunity to respond. The parties agree that, if the Court permits a response, Plaintiffs will file their response letter by August 17. The parties agree that formal briefing is unnecessary and that Defendants' request will be ripe for decision after Plaintiffs file their response letter. In light of the September 9 premarket application deadline, Defendants respectfully ask that the Court decide their request as expeditiously as feasible.

Defendants thank the Court for its attention to this matter.

Respectfully submitted,

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